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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,268	07/07/2005	John L Schenk	XY-lowPressure-USNP	5591
33549	7590	01/10/2008	EXAMINER	
SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521			NOBLE, MARCIA STEPHENS	
		ART UNIT	PAPER NUMBER	
		1632		
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		01/10/2008	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/523,268	SCHENK ET AL.
	Examiner Marcia S. Noble	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 October 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8,31 and 39-64 is/are pending in the application.
  - 4a) Of the above claim(s) 41-64 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 31, 39, 40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Status of Claims***

1. The supplemental amendment, filed 10/25/2007, to Applicant's response filed 8/27/2007 is acknowledged. Applicant's response, filed 8/27/2007 amends claims 1, 5, 14-16, 21-23, 31, 39, and 40. The supplemental amendment, filed 10/25/2007, further amends claims 1, 31, and 47 and cancels claims 9, 14-16, 21-24, 27, 30, 32, 33, and 36. Claims 1-8, 31, and 39-64 are pending.

***Election/Restrictions***

2. Claims 41-64 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/28/2005.

Claims 1-8, 31, 39 and 40 are under consideration.

***Information Disclosure Statement***

3. The information disclosure statements were filed on 1/31/2005, 2/14/2006, 3/29/2007, and 8/29/2007. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

The information disclosure statement (IDS) filed after the mailing date of on 10/25/2007. The submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the information disclosure statement is being considered by the examiner. However, CN 100998524A was not considered because it was in a language other than English and therefore was crossed out.

***Specification***

4. The objection to the specification for multiple tables that are designated "Table 1" is withdrawn because the specification has been corrected in the amendment to the specification, filed 8/27/2007.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8, 31, and 39-64, as amended and previously presented, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the remarks, filed 8/27/2007, Applicant states that the Assignee submits that the claims are enabling to one skilled in the art because the specification provided examples of how to control sperm fertility characteristics through adjustment of fluid

sheath and teaches different fluid sheath compositions (see page 13 of response filed 8/27/2007).

The arguments have been fully considered and are not found persuasive.

Applicant amended the claims to now specifically associate a specific psi with a specific sex characteristic and therefore addresses the first issue of enablement.

However, as previously stated in the Office Action, mailed 2/26/2007 on page 5, "The art teaches sperm cells are extremely delicate cells and that the full extent of the sperm cells' sensitivities have not yet been fully explored (WO99/33956, p. 3, last par; of record) and that even though a sperm cell may appear to pass through flow cytometry with no discernable side-effect, in fact, the cells themselves may have been stressed to a point that they perform less than optimally in inseminations (p. 4, lines 1-4). WO 99/33956 also teaches that a multitude of factors may be affecting sperm cell function during sorting or during assessing a sex characteristic. The art teaches that fluid sheath composition used for sorting can affect sperm cell function and seems to be species specific. The art discloses that citrate consistency for bovine sperm is important for sperm cell viability and insemination success. In contrast equine sperm seems to be hypersensitive to citrate and therefore it is suboptimal for its use with equine sperm. They also teach that a HEPES buffer consistency is necessary for optimal function and sorting of equine sperm (p. 12 and 14).

Therefore, the art suggest that there are species specific factors that affect the success of cell sorting method to produce sperm cell that have optimal sex characteristics. The claims do encompass the use of some different sheath fluid

compositions, however, the claims do not specify the essential element of which sheath fluid to use for a given species."

The claims as amended still encompass any species. However, as previously discussed in the previous Office Action and above, the art and specification suggest species differences that affect the claimed method. However, these differences are not reflected in the claims. Therefore, because the instant claims do not define the specific parameters of a fluid sheath composition in relation to the species differences disclosed in the specification and in the art; the claims still encompass embodiments that do not function because not all fluid sheath compositions will function for a given species. Therefore, the instant claims are still not enabled.

Therefore, because the breadth of the instant claims encompass non-functional embodiments because the claims do not provide a specific relationship between the different fluid sheath pressures and compositions and a given sex characteristic in a given species of animal, the instant claims are still not enabled and the instant rejection is maintained.

It is further noted that the supplemental response filed 10/25/2007 did not provide traversal arguments to this rejection.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The rejection of claims 5, 6, 14-16, 21-23, 31, 39, and 40, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

Claim 5 recited the limitation "sheath fluid stream" in line 2, which had insufficient antecedent basis for this limitation in the claim. Applicant amended the claims to recite said sheath fluid stream and now has sufficient antecedent basis. Therefore, this point of rejection is withdrawn.

Claims 14, 15 and 16 recited the limitation "said bovine semen" and "said male of a bovine species of mammal". These claims are now canceled and the rejection is moot. Therefore, the rejection is withdrawn.

Claims 21, 22, 23 recite the limitation "said equine semen" and "said male of a equine species of mammal". These claims are now canceled and the rejection is moot. Therefore, the rejection is withdrawn.

Claim 31, 39 and 40 recites the limitation "said bovine species". These claims now recite a bovine species, which has antecedent basis. Therefore, the rejection is withdrawn.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, and 8, as amended and previously presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS).

Applicant traverses this ground of rejection on the ground that Rath et al does not teach adjusted fluid stream flow through the adjustment of pressure (see page 15 of remarks filed 8/27/2007).

Applicant's argument is not found persuasive because the breadth of "adjusting" or "altering" a flow characteristic encompasses multiple situations, such as setting a fluid pressure to one psi or a series of psis, and solely stating adjusting or altering does not distinguish the instant invention from the art.

The amended claims encompass selecting the sex characteristic, viability, and altering flow characteristic wherein said fluid stream pressure is adjusted to about 40 psi when viability is selected. Rath et al teaches sperm selected at 40 psi that have improved embryo formation in *in vitro* fertilization. Embryo formation would be considered a measure of sperm viability. Therefore, the claims are still anticipated by Rath et al. and the rejection of record is maintained.

8. Claims 1-3, 5-8, 31, 39, and 40, as amended and previously presented are rejected under 35 U.S.C. 102(b) as being anticipated by Seidel et al (WO 99/33956 pub date:7/8/1999; of record in IDS).

Applicant traverses this ground of rejection on the ground that Seidel et al does not teach adjusted fluid stream flow through the adjustment of pressure (see page 15 of remarks filed 8/27/2007).

Applicant's argument is not found persuasive because the breadth of "adjusting" or "altering" a flow characteristic encompasses multiple situations, such as setting a fluid pressure to one psi or a series of psis, and solely stating adjusting or altering does not distinguish the instant invention from the art.

The amended claims encompass selecting the sex characteristics, sperm viability and motility, and altering flow characteristic wherein said fluid stream pressure is adjusted to about 40 psi when viability is selected and about 30 psi when motility is selected.

Seidel discloses a general method of sorting sperm (p. 9 and 10). Seidel discloses that the flow cytometry for sperm sorting can be adjusted to 50 or 60 psi (p. 11, lines 22-24). Seidel discloses a method of measuring motility and viability in sperm (p. 20) as well.

Because the claims recite "about" 40 psi for viability and the specification does not define a range that would be encompassed by "about 40 psi", 50 or even 60 psi would be encompassed by "about 40 psi", given its broadest reasonable interpretation.

Therefore, the claims are still anticipated by Seidel et al. and the rejection of record is maintained.

9. Claims 1-4, 8, 9, 39, and 40, as amended and previously presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Beyhan et al (Theriogenology 53:35-48, 1999; of record).

Applicant traverses this ground of rejection on the ground that Beyhan et al does not teach adjusted fluid stream flow through the adjustment of pressure (see page 15 of remarks filed 8/27/2007).

Applicant's argument is not found persuasive because the breadth of "adjusting" or "altering" a flow characteristic encompasses multiple situations, such as setting a fluid pressure to one psi or a series of psis, and solely stating adjusting or altering does not distinguish the instant invention from the art.

The amended claims encompass selecting the sex characteristic, viability, and altering flow characteristic wherein said fluid stream pressure is adjusted to about 40 psi when viability is selected. Beyhan et al teaches sperm selected at 40 psi that have improved embryo formation in *in vitro* fertilization. Embryo formation would be considered a measure of sperm viability. Therefore, the claims are still anticipated by Beyhan et al. and the rejection of record is maintained.

10. The rejection of claims 1-3, 8, 9, 14-16, 21-24, and 27, under 35 U.S.C. 102(a) as being anticipated by Suh and Schenk (Theriogenology 53(1):516, Jan 2003; of record), is withdrawn.

Applicant submits that the instant art is not prior art because the instant invention claims priority to foreign priority document 60/400,971, filed 8/1/2002. Applicant's argument is found persuasive and therefore the rejection of record is withdrawn.

11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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